

Appl. No.: 10/681,477
Group Art Unit: 1626
Applicant's Response to Paper No. 1

REMARKS

Claims 1-9 are currently pending in the present application.

In Paper No. 1, the Examiner indicates that claims 1 and 3-9 are allowed.

However, in Paper No. 1, the Examiner rejects claim 2 under 35 U.S.C. §112, second paragraph, as being indefinite. Specifically, the Examiner contends that the term "comprises" in line 2 of the claim renders the entire claim indefinite. The Examiner argues that, "[t]he term is an open-ended term, which cannot be used in reference to a compound (succinic acid)." (*See*, Paper No. 1, p. 2). Applicant respectfully traverses the rejection and the arguments and contentions set forth in support thereof for the following reasons.

At the outset, Applicant would like to highlight what appears to be a misunderstanding on the part of the Examiner and offer a corrected view. The Examiner appears to believe that the term "comprises" in claim 2 "refers" to succinic acid. This is not accurate. The term "comprises" in claim 2 refers to "the tocopherol dibasic acid hemiester starting material". More precisely, from a grammatical standpoint, --comprises-- is the verb of the subject --material--. In other words, the starting material comprises the object of the sentence, namely "tocopherol succinic acid".

Claim 2 of the instant application reads as follows:

"2. The method according to claim 1, wherein the tocopherol dibasic acid hemiester starting material comprises tocopherol succinic acid."

It is undeniably clear from the plain language of the claim that "the tocopherol dibasic acid hemiester starting material" comprises, **or in other words --includes--**, tocopherol succinic acid. However, it could also include, for example, other tocopherol dibasic acid hemiester starting materials, such as, tocotrienol succinic acid, tocodienol succinic acid, tocopherol maleic acid, and/or tocopherol azelaic acid, and/or additional non tocopherol compounds such as antioxidants or natural impurities present in the tocopherol source.

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Claim 1 of the instant application, from which claim 2 directly depends, reads as follows:

"1. A method of preparing a salt of a tocopherol dibasic acid hemiester, said method comprising:
(a) providing (i) a tocopherol dibasic acid hemiester starting material and (ii) a divalent metal salt; and
(b) reacting the tocopherol dibasic acid hemiester starting material and the divalent metal salt in a supercritical fluid medium."

In direct contradiction to well established U.S. patent claim interpretation standards, and contrary to precedent set by the Court of Appeals for the Federal Circuit (including a recent case already brought to the Examiner's attention by Applicant's undersigned representative), the Examiner has argued that Applicant's use of the indefinite article "a" with reference to "a tocopherol dibasic acid hemiester starting material" limits the term to a single material.

Applicant submits that the claim term "a tocopherol dibasic acid hemiester starting material" refers to one or more tocopherol dibasic acid hemiester starting materials. This position is well-founded and supported by both the law and the Specification.

As to the Specification, Applicant would like to draw the Examiner's attention to page 3, line 17 of the instant Specification, through page 4, line 5 thereof, which reads as follows:

"Tocopherol dibasic acid hemiester starting **materials** which are useful in the processes according to the present invention are based upon **dibasic acid hemiesters of one or more tocopherol compounds**. As used herein, the term "tocopherol compounds" refers to the broad class of compounds that can be characterized as derivatives of 6-chromanol having an isoprenoid side chain, of which many are known to exhibit vitamin E activity. These compounds include, for example, the alpha (α -), beta (β -), gamma (γ -) and delta (δ -) homologues of tocopherol, as well as unsaturated derivatives, such as, tocomonoenols, tocodienols and tocotrienols. The tocopherol dibasic acid hemiester starting **materials** which are useful in the processes according to the

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present invention may be synthetic or naturally-derived, and may include either optical enantiomer of any of the aforementioned homologues, or mixtures thereof. In preferred embodiments of the present invention, naturally-derived tocopherol starting materials are used. Preferably the tocopherol starting materials used in the processes according to the present invention include *d*- α -tocopherol compounds, most preferably *d*- α -tocopherol succinic acid. Mixtures of naturally-derived tocopherols may also be used, such as, for example, mixtures of alpha (α -), beta (β -), gamma (γ -) and/or delta (δ -) tocopherol." (See, Applicant's Specification, p. 3, line 17 *et seq.* (emphasis added)).

Applicant respectfully submits that it is clear from the Specification that mixtures of two or more different tocopherol dibasic acid hemiester starting materials, in addition to single tocopherol dibasic acid hemiester starting materials, are contemplated and embraced by the description of the invention. There is no language in the instant Specification which would lead one of ordinary skill in the art to conclude that only singular starting materials can be used. In fact, to the contrary, it is clear that mixtures of starting materials can be used.

Moreover, as mentioned above, U.S. law clearly supports Applicant's position that the indefinite article "a", when used to introduce a claim element, refers to one or more of that element, unless clearly indicated as meaning only the singular. Most recently, in KCI Corporation v. Kinetic Concepts, Inc., the Court of Appeals for the Federal Circuit has held, as follows:

"[t]his court has repeatedly emphasized that an indefinite article "a" or "an" in patent parlance carries the meaning of 'one or more' in open-ended claims containing the transitional phrase 'comprising.' See *Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 977, 52 U.S.P.Q.2D (BNA) 1109, 1112 (Fed. Cir. 1999); *AbTox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1023, 43 U.S.P.Q.2D (BNA) 1545, 1548 (Fed. Cir. 1997); *North Am. Vaccine, Inc. v. American Cyanamid Co.*, 7 F.3d 1571, 1575-76, 28 U.S.P.Q.2D (BNA) 1333, 1336 (Fed. Cir. 1993); see also Robert C. Faber, Landis on Mechanics of Patent Claim Drafting 531 (3d ed. 1990)."

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(*See, KCJ Corp. v. Kinetic Concepts, Inc.*, 223 F.3d 1351, 55 USPQ.2d 1835 (CAFC 2000) (emphasis added)).

The KCJ Court went on to state that, "the article 'a' receives a singular interpretation **only in rare circumstances** when the patentee evinces a **clear intent** to so limit the article." (*See, id.* at 1356 (citations omitted) (emphasis added)). The Examiner has not pointed to any part of the Specification which could be argued to "evince a clear intent to so limit the article." To the contrary, as set forth above, the instant Specification clearly contemplates mixtures of starting materials, *i.e.*, plural materials.

Furthermore, the quintessential treatise on U.S. claim drafting, Faber's Landis on Mechanics of Patent Claim Drafting, which was specifically cited by the KCJ Court, flatly states with reference to plural claim elements that, "[w]here one or more [element] will function, then one merely claims 'a' member and this covers more than one." (*See, Faber, Robert C., Landis on Mechanics of Patent Claim Drafting*, 4th Ed., §20 (Practicing Law Institute, New York, NY 1996)).

Applicant submits that the law in this regard is clear. The indefinite article "a" or "an" means one or more when used with the transitional phrase comprising, unless it is clear that Applicant intended otherwise.

The Examiner's argument that the transitional phrase "comprising" in claim 1 refers only to the method, and not the elements of the recited steps, is tenuous at best. A U.S. patent claim has **one** preamble, **one** transition word, and **one** body. When an applicant chooses to employ the open-ended transitional word "comprising", it is meant to be just that – open-ended. Simply put, the claim requires the elements set forth in the body, but is not limited to only those elements. According to the Examiner's argument, one would need to include a transitional word preceding each and every element of the claim. Such an outcome would be confusing and would quite possibly result in a claim that is in fact indefinite.

There is simply no basis in law, nor any evidence in the instant Specification, to support the Examiner's conclusion that the term "a tocopherol dibasic acid hemiester starting material" refers to only a single material.

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In the event the Examiner is unconvinced that his conclusion is in error, Applicant's undersigned representative respectfully requests a telephone conversation with the Examiner and his supervisor.

In view of the remarks set forth above, Applicant submits that all pending claims fully comply with the requirements of 35 U.S.C. §112, second paragraph. Accordingly, reconsideration, withdrawal of the rejection and a Notice of Allowance for all pending claims are respectfully requested.

Respectfully submitted,

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(Date)

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